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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(781)279-1675 FAX: (781)279-1742

WARNING LETTER

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

NWE-12-98 W

June 12, 1998

Wayne M. Henry
President
Alerchek, Inc.
203 Anderson Street
Portland, ME 04101

Dear Mr. Henry,

During an inspection of your firm located in Portland, Maine on May 18 & 19, 1998, our investigator determined that your firm is responsible for the manufacture and distribution of a medical device, Alerchek, Inc. Total Human IgE test kit. This product is a medical device as described by section 201 (h) of the Federal Food, Drug and Cosmetic Act. (The Act).

The above stated inspection revealed that this device is adulterated within the meaning of Section 501 (h) of The Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage or installation are not in conformance with the Quality System Regulations, as specified in Title 21 Code of Federal Regulations, (21 CFR) Part 820, as follows:

1. Failure to establish procedures for and to conduct quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. (21 CFR 820.22)

2. Failure to establish and maintain procedures for complaint handling, purchasing controls, document controls, and the creation of a Device Master record. (21 CFR 820.40)

3. Failure to maintain complaint files and procedures for receiving, reviewing and evaluating complaints. (21 CFR 820.198)

Our files show that we wrote to you in 1987 and 1989 and pointed out many of these same deficiencies. In a response letter you wrote to the FDA in October, 1989, you stated many of these deviations had been resolved.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the close-out of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. Your are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective action.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct the deviations discussed in this letter. Failure to promptly correct these deviations may result in regulatory action by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office within fifteen (15) days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including and explanation of each step being taken to prevent the recurrence of similar violations. Your response should be sent to E. Frank Gesing, Compliance Officer, United States Food and Drug Administration, One Montvale Avenue, Stoneham, Massachusetts 02180.

If you have any questions concerning this matter, please contact Mr. Gesing at 781-279-1675, Extension 127.

Sincerely yours,

[Sig]

John R. Marzilli
District Director
New England District Office